510(k) Summary

AUG 19 2011

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.87 (b)

Product Name: Trident Specimen Radiography System, Model: RC

Product Classification Name: Cabinet X-Ray System

Product Classification Code: MWP **CFR Section:** 892.1680

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36-37 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Deborah Thomas
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Date Prepared: May 27, 2011

Predicate Devices:

K083510 Kubtec XPERT 40 Specimen Radiography System

K061361 Faxitron DX-50 Specimen Radiography System

Device Description:

The Trident Specimen Radiography System is a self-contained, direct digital imaging system for imaging small to medium sized surgical and biopsy specimens. The system includes an X-ray generator, X-ray tube (microfocus), a-Se digital detector, 12 x 14 cm active imaging area, exposure timer, specimen chamber, control panel and an acquisition workstation. The lower 1/3 of the workstation's display monitor is the graphical user interface for the system. The upper 2/3 of the monitor is the display for the specimen radiographs. The system includes automatic exposure control functionality, but manual exposure techniques can also be selected. The magnification tray can be adjusted and will allow images to be produced at 1.5 and 2.0 X magnifications.

The system is self-contained. Shielding is incorporated within the cabinet chamber system design, eliminating the need for separate additional shielding. The unit is mounted on a cart to be easily transported.

Indications for Use:

A cabinet x-ray system used to provide digital x-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the biopsy procedure.

Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the time the patient needs to be under examination.

Comparison with Predicate Devices:

The Trident Specimen Radiography System and predicate devices, Kubtec XPERT 40 Specimen Radiography System K083510, and the Faxitron DX-50 Specimen Radiography System K061361, have the same intended use, general configuration, principles of operation, and similar operating parameters.

Summary of Testing

The Trident Specimen Radiography System was successfully tested by UL to ISO 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use and by TUV Rheinland to EMC Directive 2004/108/EC.

Hologic successfully performed design control verification and validation tests in accordance with 21 CFR Part 820 and 21 CFR 1020.40 Cabinet X-Ray Systems.

Conclusion

The Trident Specimen Radiography System design, operation, construction and materials are similar to existing marketed device with no additional risks or hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Deborah Thomas
Senior Regulatory Affairs Specialist
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

AUG 19 2011

Re: K111508
Trade/Device Name: Trident Specimen Radiography System, Model: RC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: July 29, 2011
Received: August 1, 2011

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Premarket Notification: Trident Specimen Radiography System

510(k) No.

Device Name: Trident Specimen Radiography System, Model: RC

Indications For Use

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111508